

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

NOVARTIS PHARMACEUTICALS CORPORATION,
NOVARTIS CORPORATION, NOVARTIS AG, and
NOVARTIS PHARMA AG,

Plaintiffs,

v. // CIVIL ACTION NO. 1:14CV111
(Judge Keeley)

MYLAN INC. and MYLAN PHARMACEUTICALS,
INC.,

Defendants.

ORDER DENYING PLAINTIFFS' MOTION TO STAY PENDING RESOLUTION OF
JURISDICTIONAL CHALLENGE TO FIRST-FILED DELAWARE CASE
(Dkt. No. 29)

On June 26, 2014, the plaintiffs, Novartis Pharmaceuticals Corporation, Novartis Corporation, Novartis AG, and Novartis Pharma AG (collectively, "Novartis"), filed a complaint for patent infringement against defendants Mylan Inc. and Mylan Pharmaceuticals Inc. (collectively, "Mylan") (Dkt. No. 1).¹ Mylan filed its answer and counterclaim on December 4, 2014 (Dkt. No. 31), and Novartis filed its answer to the counterclaim on December 23, 2014 (Dkt. No. 36).

On November 24, 2014, Novartis filed a motion to stay this case as a second-filed suit² until resolution of a jurisdictional

¹ The day before, on June 25, 2014, Novartis had filed an identical complaint in the United States District Court for the District of Delaware, making the suit in this district a second-filed action (Dkt. No. 30 at 6, Dkt. No. 30-3).

² A second-filed case, or protective suit, is usually filed by the patent holder to protect its entitlement to a thirty-month stay

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dispute in the first-filed suit pending in the United States District Court for the District of Delaware (Dkt. No. 29). Mylan filed its response in opposition to Novartis' motion on December 8, 2014 (Dkt. No. 34), and Novartis filed its reply on December 15, 2014 (Dkt. No. 35). The motion is now fully briefed and ripe for disposition.

I. Background

Novartis holds two patents³ and a new drug application ("NDA") for EXJADE, a drug "indicated for the treatment of chronically elevated levels of iron in the blood caused by repeated blood transfusions."⁴ (Dkt. No. 1 at 6-7). EXJADE is a tablet for oral suspension with the active ingredient deferasirox. U.S. Food and Drug Administration, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, available at

should the first-filed suit be dismissed.

³ Patent No. 6,465,504 ("the '504 Patent"), issued on October 15, 2002, and Patent No. 6,596,750 ("the '750 Patent"), issued on July 22, 2003, cover EXJADE (Dkt. No. 1 at 1, 6-7).

⁴ For a description of EXJADE and its indications, see http://www.us.exjade.com/index.jsp?usertrack.filter_applied=true&NovaId=2935376999746121108 (last visited Jan. 29, 2015).

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<http://www.accessdata.fda.gov/scripts/cder/ob/docs/temptn.cfm> (last updated Jan. 28, 2015).

On May 13, 2014, Mylan notified Novartis⁵ that it had filed an abbreviated new drug application ("ANDA") containing a Paragraph IV certification that Novartis' patents for EXJADE are invalid, unenforceable, or will not be infringed by its ANDA.⁶ On June 26, 2014,⁷ Novartis filed its complaint alleging patent infringement, and seeking various forms of relief, including: 1) a judgment that Mylan infringed its patents; 2) a judgment that the patents are valid and enforceable; 3) an order stating that the effective date of any FDA approval of Mylan's ANDA should be after Novartis'

⁵ Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), an ANDA-filer must notify the patent holder if it plans to put a generic drug on the market pursuant to § 355(j)(2)(A)(vii)(iv), colloquially referred to as "Paragraph IV."

⁶ When a generic manufacturer files an ANDA, it must certify one of four conditions regarding the patent status of the brand drug: (1) that patent information for the brand drug has not been filed; (2) that the patent has expired; (3) the date on which the patent will expire; or, (4) that the patent is invalid, or will not be infringed by the manufacture, use, or sale of the generic drug. 21 U.S.C. § 355(j)(2)(A)(vii).

⁷ If the patent holder files suit within 45 days of receiving an "ANDA letter" such as the one sent by Mylan, it triggers a thirty-month stay, during which the FDA cannot approve or deny the ANDA. 21 U.S.C. § 355(j)(5)(B)(iii).

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patents expire; 4) an injunction restraining Mylan from manufacturing, using, offering to sell, or selling a generic version of EXJADE; 5) damages; and, 6) costs and reasonable attorneys' fees (Dkt. No. 1 at 10-11).

On December 4, 2014, Mylan filed its answer and counterclaim, denying any infringement of Novartis' patents, and countering that the patents are invalid (Dkt. No. 31 at 17-26). Mylan seeks a declaration that its manufacture, use, offer for sale, importation, or sale of its generic version of EXJADE does not infringe Novartis' patents, a declaration that the patents are invalid, dismissal of Novartis' complaint with prejudice, as well as attorneys' fees and costs. *Id.* at 26-27.

When Novartis filed its motion to stay the second-filed case on November 24, 2014, it argued that this Court should stay the case under the first-to-file rule⁸ until the District of Delaware could resolve a pending jurisdictional dispute in the first-filed case (Dkt. No. 30 at 5). Prior to that, on August 6, 2014, Mylan had filed a motion in Delaware seeking to dismiss the first-filed

⁸ The first-to-file rule, explained in Section II, generally provides that the court with the first-filed action should retain jurisdiction.

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case based on lack of jurisdiction (Dkt. No. 34-1). To date, the District of Delaware has not ruled on Mylan's motion (Dkt. No. 30 at 7). Therefore, Novartis contends, this Court should stay the second-filed suit until the jurisdictional dispute in Delaware is resolved. If that court rules that it has jurisdiction over Mylan, the case will proceed there; if it does not have jurisdiction, however, the case will proceed in this Court, where there is no question that personal jurisdiction exists.

In Mylan's response in opposition to Novartis' motion, it argues that the first-to-file rule does not apply because the issue of personal jurisdiction is not settled in Delaware, and that Novartis is simply seeking to delay generic entry of Mylan's product (Dkt. No. 34 at 5-6).

It is important at this juncture to note that the jurisdictional dispute in the District of Delaware is significantly complicated by recent precedent. In AstraZeneca AB v. Mylan Pharma, Inc., 2014 WL 5780213 at *1 (D. Del. Nov. 5, 2014), another first-filed suit with Mylan named as the defendant, the District of Delaware concluded that it lacked general personal jurisdiction over Mylan, but that specific personal jurisdiction existed due to Mylan's contacts with Delaware. Id. at *7. The court granted

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Mylan's request to certify an interlocutory appeal, recognizing that "a controlling (and novel) question of law" existed "for which there is substantial ground for difference of opinion." AstraZeneca AB v. Aurobindo Pharma Ltd., 2014 WL 7533913 at *1, fn 1 (D. Del. Dec. 17, 2014).

Novartis and Mylan each reference the Astrazeneca decision in an attempt to persuade the Court either to grant or deny the stay. Novartis argues that, using the same rationale as in Astrazeneca, Mylan will be subject to personal jurisdiction in Delaware in the first-filed suit (Dkt. No. 35 at 5), and the Court should stay the second-filed suit because it is squarely within the first-to-file rule. Id. at 6. It contends that whether Delaware has personal jurisdiction over Mylan in the first-filed suit is not at issue here. Id. at 6, 12.⁹

Mylan, on the other hand, asserts that the factual situation in the first-filed suit is significantly different from that in Astrazeneca, and, as a result, the Delaware court will not have

⁹ The Court agrees that whether the District of Delaware has personal jurisdiction over Mylan is not at issue here, and declines to weigh in on that dispute.

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jurisdiction over it (Dkt. No. 34 at 9-10). It urges the Court to deny Novartis' motion to stay in order to avoid further delay.

II. Applicable Law

A. First-to-File Rule

The first-to-file rule is an equitable doctrine that "favors the forum of the first-filed action" Genentech, Inc. v. Eli Lilly and Co., 998 F.2d 931, 937 (Fed. Cir. 1993), abrogated on other grounds, Wilton v. Seven Falls Co., 515 U.S. 277, 115 S.Ct. 2137 (1995). The primary policies underlying the first-to-file rule are the avoidance of duplicative litigation, the promotion of uniformity of results, and the conservation of judicial resources. See Colorado River Water Conservation District v. United States, 424 U.S. 800, 817, 96 S.Ct. 1236 (1976); Cadle Co. v. Whataburger of Alice, Inc., 174 F.3d 599, 604 (5th Cir. 1999).

When two courts have concurrent jurisdiction in substantially identical cases, the court hearing the second-filed action generally defers to the court hearing the first-filed action. See Merial Ltd. v. Cipla Ltd., 681 F.3d 1283, 1299 (Fed. Cir. 2012). Courts usually consider three factors to determine whether the first-to-file rule applies. These include 1) chronology, 2)

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identity of parties, and 3) similarity of issues. Intersearch Worldwide, Ltd. v. Intersearch Group, Inc., 544 F.Supp.2d 949, 957 (N.D. Cal. 2008).

Importantly, in first-filed cases where jurisdiction is unsettled, courts have held that the first-to-file rule does not apply. See, e.g., Genentech, 998 F.2d at 938 (listing the absence of jurisdiction as a "sound reason that would make it unjust or inefficient to continue the first-filed action."); Orthmann v. Apple River Campground, Inc., 765 F.2d 119, 121 (8th Cir. 1985) (dismissing the first-filed action, where jurisdiction was "vigorously dispute[d]," to allow the second-filed action to progress).¹⁰

Some courts, however, have determined that jurisdiction in the first-filed case is just one factor to consider. See Cadle Co., 174 F.3d at 605 ("While the likelihood of a jurisdictional dispute in the first-filed court may be a factor to consider in applying

¹⁰ The parties cite this Court's opinion in Pfizer, Inc. v. Mylan, Inc., 2009 WL 10270101 at *1-2 (N.D.W. Va. Nov. 20, 2009). There, the Court applied the first-to-file rule and granted the plaintiff's motion to transfer the case to the jurisdiction of the first-filed case. Id. Unlike the facts here, however, there was no jurisdictional dispute; therefore, the first-to-file rule was fully in play.

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the rule, resolving the dispute in favor of that court's jurisdiction is never a condition precedent to applying it."); Brower v. Flint Ink Corp., 865 F.Supp. 564, 570 (N.D. Iowa 1994) (noting that jurisdictional considerations are one of many factors when determining what circumstances are compelling enough to overcome the first-to-file rule).

The first-to-file rule is subject to various exceptions, including consideration of whether the balance of convenience weighs in favor of the second-filed court's continued exercise of jurisdiction over the suit, whether the suit is filed in bad faith, or whether the suit is filed for the purposes of forum shopping. EEOC v. Univ. of Pa., 850 F.2d 969, 976 (3d Cir. 1988); Ellicott Mach. Corp. v. Modern Welding Co., 502 F.2d 178, 181 (4th Cir. 1974). It is the province of the first-filed court, however, to determine "whether an exception to the first-filed rule applies." Touchstone Research Lab, Ltd. v. Anchor Equip. Sales, Inc., 294 F.Supp.2d 823, 828 (N.D.W. Va. 2003) (quoting Citigroup Inc v. City Holding Co., 97 F.Supp.2d 549, 557 n.4 (S.D.N.Y. 2000)).

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B. Motion to Stay

Trial courts generally have broad discretion to stay proceedings incident to their power to control their own dockets. Landis v. North American Co., 299 U.S. 248, 254, 57 S.Ct. 163, 165-66 (1936). The proponent of a stay bears the burden of proving its necessity. Id. at 255, 57 S.Ct. at 166. Factors for the court to consider include "'(1) the interests of judicial economy; (2) hardship and equity to the moving party if the action is not stayed; and (3) potential prejudice to the non-moving party.'" Tolley v. Monsanto Co., 591 F.Supp.2d 837, 844 (S.D.W. Va. 2008) (quoting Meyers v. Bayer AG, 143 F.Supp.2d 1044, 1049 (E.D. Wis. 2001)).

III. Legal Analysis

The prerequisites for applying the first-to-file rule, chronology, identity of parties, and similarity of issues, seem to be satisfied here. Intersearch Worldwide, Ltd., 544 F.Supp.2d at 957. First, the first-filed complaint was filed in the District of Delaware on June 25, 2014 (Dkt. No. 30 at 6). The second-filed complaint was filed in this Court on June 26, 2014, the following day (Dkt. No. 1). Second, the parties in the first-filed case are

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the same parties as those in this case (Dkt. No. 30 at 8). Finally, the complaints, the patents, and the allegedly infringing products are all identical. Id. Shire U.S., Inc. v. Johnson Matthew, Inc., 543 F.Supp.2d 404, 408-09 (E.D. Penn. 2008) (noting that the subject matter requirement is met where the actions involve the same patent and the same infringing product).

Mylan argues that the first-to-file rule should not apply due to the jurisdictional dispute in play in the District of Delaware. Although the Fourth Circuit has not spoken to this exact issue, both the Federal Circuit and the Eighth Circuit have listed the lack of jurisdiction, or a dispute over jurisdiction, as sound reasons for refusing to stay or transfer the second-filed case. See Genentech, 998 F.2d at 938; Orthmann, 765 F.2d at 121. See also Kerotest Manufacturing Co. v. C-O-Two Fire Equipment Co., 342 U.S. 180, 183 72 S.Ct. 219, 221 (1952) (cautioning against "rigid mechanical solution[s]" to forum problems).

In Orthmann, the Eighth Circuit declined to apply the first-to-file rule, and dismissed the first-filed action instead, where jurisdiction was "vigorously" disputed. 765 F.2d at 121 ("We conclude that the federal comity doctrine is best served in this case by dismissing Orthmann's action in [the first-filed court]. .

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. [w]e note that while none of the parties question whether the Wisconsin court has personal jurisdiction, the parties vigorously dispute whether there is personal jurisdiction over the defendants in Minnesota."). The reasoning in Genentech and Orthmann is persuasive that a serious jurisdictional dispute is a "sound reason that would make it unjust or inefficient to continue the first-filed action." Genentech, 998 F.2d at 938.¹¹ See Novartis v. Mylan, Case No. 1:14CV106, Dkt. No. 47 (Jan. 27, 2015) (denying plaintiffs' motion to stay the second-filed suit under almost identical circumstances to those here).

In the alternative, Novartis argues that the Court should exercise its discretion to stay the case (Dkt. No. 30 at 11). First, it contends that the interests of judicial economy favor granting a stay because Mylan will not suffer undue hardship by litigating in Delaware, and because that court is already familiar with the EXJADE patents. Id. at 10-11. It notes that only a slight delay is possible, even if Mylan prevails in its

¹¹ The Court declines to consider whether the balance of convenience favors Mylan, as that calculation is the province of the court presiding over the first-filed case. Touchstone Research Lab, 294 F.Supp.2d at 828.

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jurisdictional challenge in Delaware and before the merits in this Court. *Id.* at 11-12. It also argues that it will suffer significant prejudice if a stay is not granted because it "will be forced to litigate two identical cases, seeking the same relief in two district courts." *Id.* at 12.

For its part, Mylan contends that the interests of judicial economy do not favor a stay because the first-filed case "is still in the pre-Answer stage," whereas Mylan "is ready to proceed with litigation in this Court. . . ." (Dkt. No. 34 at 13). Furthermore, any action in this Court "will shorten the time needed in Delaware" should the jurisdictional dispute be resolved in favor of Novartis. *Id.* Mylan asserts that Novartis will not face any hardship if the Court denies its motion to stay because it chose to litigate in this Court by filing a protective suit. *Id.* at 12. Finally, Mylan argues that it will suffer significant harm because a stay may delay the launch of its generic beyond thirty months.¹² *Id.* at 11.

¹² As already noted, Novartis received a thirty-month stay because it filed suit within 45 days of receiving Mylan's ANDA letter.

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After carefully weighing the factors of judicial economy, hardship or inequity to Novartis, and potential prejudice to Mylan, the Court concludes that a stay is inappropriate. First, judicial economy would be best advanced by moving forward with the suit. Even if the Court later transfers the second-filed suit to the District of Delaware, it can resolve any discovery disputes and move the lawsuit along in the interim. This is especially important because Mylan is faced with the possibility of both a stay in this case and a long wait in the District of Delaware should that court choose to withhold its decision on Mylan's motion to dismiss until the Federal Circuit decides the interlocutory appeal in AstraZeneca.¹³

Second, Novartis will not suffer hardship or inequity by litigating here. It filed suit in this Court as a protective measure, and cannot fairly complain because the suit is progressing here now. It will not "be forced to litigate two identical cases" if, once the District of Delaware resolves the jurisdictional

¹³ The Court notes the December 31, 2014, letter from Mylan indicating that, if the Federal Circuit granted an interlocutory appeal, the jurisdictional dispute in AstraZeneca likely would not be resolved until late 2015. Even if the District of Delaware does rule on the jurisdictional dispute before AstraZeneca is decided, that ruling could still be many months away.

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dispute, it refiles its motion in this Court for a transfer or stay (Dkt. No. 30 at 12).

Finally, Mylan could suffer significant harm if the Court grants the stay. Aside from the fact that a decision on Mylan's motion to dismiss in the first-filed case may not be "imminent," as Novartis suggests, the possibility of extensive litigation beyond the thirty-month stay period exists (Dkt. No. 35 at 5). Although Novartis suggests that the parties start discovery pending a decision on the motion to dismiss, the parties would be without a remedy if any discovery disputes arose. *Id.* at 9.

For the reasons discussed, the Court **DENIES** Novartis' motion to stay the second-filed suit (Dkt. No. 29), duly noting that Novartis is free to file a second motion to stay, or a motion to transfer, should the District of Delaware resolve the jurisdictional dispute in its favor.

Having disposed of the motion, the Court **CANCELS** the status conference set for **Monday, February 2, 2015, at 12:15 P.M.**

It is so **ORDERED**.

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The Court directs the Clerk to transmit copies of this Order to counsel of record.

DATED: January 29, 2015.

/s/ Irene M. Keeley
IRENE M. KEELEY
UNITED STATES DISTRICT JUDGE